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K022120
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## 510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

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|---|---|
| Contact: | PLUS ORTHOPEDICS<br>6055 Lusk Blvd.<br>San Diego, CA 92121<br>Tel: 858-550-3800 x 2506<br>Attn: Mr. Hartmut Loch, RAC<br>Director, Regulatory Affairs |
| Trade name: | MPF Acetabular Cup Generation 2 |
| Common name: | Acetabular Cup |
| Classification name: | Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous - Product Code: LZO - 888.3358<br>Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented - Product Code: LWJ<br>§ 888.3353 - Class II - 87 Orthopedic Device Panel |
| Predicate Device: | MPF Acetabular Cup, K011836 - S/E 9/7/01 |
| Device Modification Description: | We have added 10 sizes MPF Standard Cup (without screw holes), sizes 46 mm to 64 mm in 2 mm increments and 14 sizes MPF Revision Cup (with 10 screw holes), sizes 46 mm to 72 mm in 2 mm increments.<br><br>In addition, we have included the following PE inserts:<br>5 insert for 28 mm ball heads, sizes 39 mm, 41 mm, 44 mm, 48 mm and 52 mm outside diameter,<br>3 inserts for 32 mm ball heads, sizes 44 mm, 48 mm and 52 mm outside diameter,<br>5 hooded insert for 28 mm ball heads, sizes 39 mm, 41 mm, 44 mm, 48 mm and 52 mm outside diameter<br>3 hooded insert for 32 mm ball heads, sizes 44 mm, 48 mm, and 52 mm outside diameter<br><br>Instead of 7 sizes non-sterile cancellous (spongiosa) bone screws, sizes 20 mm to 50 mm in 5 mm increments for the predicate device, 6 sterile cancellous (spongiosa) bone screws, sizes 25 mm to 50 mm in 5 mm increments are now available with the MPF 2nd generation cup: |
| Indications: | The MPF Acetabular Cup is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2002

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
Plus Orthopedics
6055 Luck Boulevard
San Diego, CA 92121-2700

Re: K022120
Trade Name: MPF Acetabular Cup Generation 2
Regulation Number: 21 CRF 888. 3353 and 888.3358
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Hip joint metal/polymer metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LZO and LWJ
Dated: June 28, 2002
Received: July 1, 2002

Dear Mr. Loch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SPECIAL 510(K) DEVICE MODIFICATION
MPF Acetabular Cup Generation 2
June 28, 2002



510(k) Number: K022120

Device Name(s): MPF Acetabular Cup Generation 2

Indications for Use:

The MPF Acetabular Cup Generation 2 is intended for uncemented use for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022120